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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,150	04/13/2004	Joseph M. Jilka	P04376US01	4559

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EXAMINER	
SALIMI, ALI REZA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,150	JILKA, JOSEPH M.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 4-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

This is a response to the amendment filed 9/26/2005. Claims 1-34 are present. Claims 1, 2, 4-28 are withdrawn from consideration as they are drawn to non-elected groups. Claim 3 has been amended. Claims 3, and 29-34 are under consideration.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 3, 29-34 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced in the previous Office Action mailed 7/05/2005. Applicant argues that the claims are not directed to vaccine development. Applicant asserts that the invention achieves protection without traditional vaccine/antibody generating protocol. Applicant argues that observed protection is not specific and is applicable to universe of antigens. Applicant admits on the record that generating plants that express antigens is known in the art, and optimization of administering the antigens is no more than routine experimentation. Applicant asserts that examples of the specification indicate administration of antigens absence of generation of antibodies. Applicant's argument as part of amendment filed 9/26/2005 has been considered fully, but they are not persuasive. At the onset Applicant is reminded that limitation of "vaccine" and "protective composition" are interchangeable. Vaccine limitation means the composition provides absolute protection against viral challenge. Hence, in reality with respect to the scope of claim 3, Applicant has not changed anything, protective response is a vaccine. Additionally, as it was articulated before to date there are no vaccines or protective compositions against many

viruses such as HIV, EBOLA, Avian Bird Flu H5N1 strain, and yet the scope of claimed invention is directed to any and all viral protection. Applicant argues that nothing short of routine experimentation would accomplish the task of enabling the full scope of the claimed invention. Yet, to date Applicant has not volunteered any data in a form of declaration to refute the Office's position. Additionally, the state of the art neither prior to date of filing or post filing set forth any teaching within the scope of claimed invention. Applicant is more than welcome to bring in auxiliary information to demonstrate that simple dosing of transgenic maize plant would protect against at least a number of different virus type. Viruses do not all follow the same path of infecting the host, or tissue sample. To determine the efficacy of Applicant's method within the whole host of viruses would indeed create undue experimentation. Applicant cannot expect others to enable the broad scope of his invention. See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). Lack of clear disclosure is not supplied by a speculation as to what one skilled in the art might do or might not do if he followed the teaching of the inventor. The disclosure should be clearer than to suggest that one skilled in the art *might* construct or observe somthing in a particular manner. The rejection is respectfully maintained.

Claim Rejections - 35 USC § 102

Claims 3, 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lam et al (WO 94/20135) for reasons of record advanced in the previous Office Actions mailed 7/5/2005. Applicant argues that lam teaches mucosal antibody production. Applicant further asserts that Lam refers to mucosal immunity as a requirement for IgG production. Additionally, Applicant

recites the mucosal definition according to Lam's disclosure on pages 3-4. Applicant's argument as part of amendment filed 9/26/2005 has been considered fully, but they are not persuasive. Applicant's understanding of Lam's teaching is misplaced. Applicant in the current application has not detected IgG in the serum only (emphasis added). Applicant never conducted any experiment that shows whether there were any IgA antibodies at gut-associated lymphoid tissues (GALT); Peyer's Patches). There is no magic in science, either there is T cell response or antibody response. Just because one does not consider all possibilities does not mean the mechanism of action is unexplainable. Applicant is encouraged to look at the claim limitation carefully. For example claim 3 indicates: "without developing serum antibodies", but Applicant in his response translate this into "NO antibody response", there is a vast difference between the two. Applicant has not detected antibody at serum level, but that does not mean that at mucosal tissue level there was no IgA production. That is what Lam is teaching. Lam says either there is IgA antibodies at tissue level (GALT) and/or IgGs at serum level depending on dosage of transgenic plant administered.

In addition, it is absolutely an unsupported assertion when Applicant says "Lam refers to mucosal immunity as the immunity where IgG antibodies are made" (see Applicant's response page 11). Lam, on the bottom of page 3 and first line of page 4, clearly indicated that IgA antibodies are associated with mucosal immunity. Those of skill in the art know that IgA is produced at lymphoid tissues in the gut, i.e. GALT. Therefore, IgA may never reach serum, but that does not mean, No antibody is formed. It all depends on the dosage. As was previously indicated, Lam et al on page 8 indicates that the mucosal immune response and/or humoral immune response. The operative phrases are "and/or", in addition to, "dose dependent manner"

(emphasis added). It means it can be mucosal or humoral depending on the dosage. It means IgA is produced at tissue level or IgG at serum level, and if you administer large enough quantity the antibodies would reach serum. This is exactly what Applicant has done. Applicant has not detected any IgG at serum level, but that does not mean no IgA was generated at tissue level. Frankly, it is not apparent from the Tables whether Applicant was even looking for IgA at serum level. If you are not doing any binding assays you can't conclude IgA was not present. According to the facts presented in the specification Applicant never looked for IgAs, and merely concluded that no antibody was generated. Lam et al is a pioneering invention, hence, they are entitled to a broad protection, they are teaching that if one wants mucosal response then one can achieve it by their method, and if one wants humoral response, then that can also be achieved, and all is needed is dosage calibration. Lam says, administer enough where only mucosal, i.e. IgA, is generated at tissue level and or administer more transgenic plant and IgG will be produced and can be detected at serum level. This is exactly what applicant is asking the Office to consider, and this is exactly what applicant has done. Moreover, Applicant is directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting, it simply has not invented anything new." This is the case here, while the Applicant may have "Observed" something interesting they have not invented anything new. The rejection is respectfully maintained.

NEW GROUND OF REJECTION:

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 recites the limitation "vaccine material" in line 2. There is insufficient antecedent basis for this limitation in the claim.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi
10/22/2005